

1083095

510 (k) Summary for the SonixTouch Ultrasound Scanner

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Devices Act of 1990 revisions to 21 CFR, Part 807.92, Content and format of a 510(k) summary.

1.0 Submitter Information

1.1 Submitter

Ultrasonix Medical Corporation
130-4311 Viking Way
Richmond, British Columbia
Canada V6V 2K9
(t) 604-279-8550
(f) 604-279-8559

OCT 31 2008

1.2 Contact

Chas Yu, Quality Assurance Manager
(t) 604-279-8550 x 152
(f) 604-279-8559
(e) chas.yu@ultrasonix.com

1.3 Date Prepared

September 1, 2008

2.0 Device Name

2.1 Common Name

Ultrasound Imaging System

2.2 Proprietary Name

SonixTouch Ultrasound Scanner

2.3 Classification Name

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

2.4 Classification

Class II

2.5 Predicate Device:

SONIX MDP Ultrasound Scanner (K080935)
SONIX Ultrasound Scanner (K061827)
SonoSite MicroMaxx High Resolution Ultrasound System (K053069)
Philips HD 11 Diagnostic Ultrasound System (K062247)
GE Logiq P5 and A5 (K060993)
Imacor Zura TEE System (K080223)
Siemens S2000 Diagnostic Ultrasound System (K072786)
Volcano S5i Family of Ultrasound Systems (K061215)

2.6 Reason for submission:

Name change request

N/A

New product clearance for:

SonixTouch Ultrasound Scanner and Transducers:	L14-5/38
	C5-2/60
	C5-2/40
	EC9-5/10
	SA4-2/24
	SA3-1/24
	L14-5W/60
	PA7-4
	BPSL9-5/55
	BPC8-4/10
	C7-3/50
	4DC7-3/40
	4DL14-5/38
	4DEC9-5/10
	L9-4/38
	MC9-4/12
	HST15-8/20
	L15-8/26
	TEM7-3/9
	TEM10-7/5
	TEEIMA
	LAP

2.7 Device description

The SonixTouch Ultrasound Scanner is a new multi-purpose mobile, software controlled diagnostic ultrasound system with on-screen thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed(PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic imaging on a Flat Panel Display. The user interface includes specialized controls, a minimized computer keyboard, and touch panel on an ergonomic console.

The system has an electrocardiography (ECG) display feature and support for a 3-lead ECG cable assembly. The systems provide measurement capabilities for anatomical structures and fetal biometry that provide information used for clinical diagnostic purposes. The system has a PW and CW audio output feature and cine review, image zoom, labeling, biopsy, measurements and calculations, image storage and review, printing, and recording capabilities. The systems include a Digital Imaging and Communications (DICOM) module which enables storage.

The system is designed for use in linear, convex and phased array scanning modes, and supports linear, convex, microconvex and phased array probes.

The biopsy kits are accessories to the SonixTouch Ultrasound Scanner. These accessories are made up of a polymeric bracket. There are features on the bracket that prevent the bracket from being oriented incorrectly when attached to the transducer. The brackets are not sterile and will be covered with a sterile sheath prior to use. These brackets are designed to accept and retain the needle guides in a mechanically secure way through the medium of the sterile sheath. The brackets are reusable. The needle guide is a separate sterile polymeric part that attaches to the bracket through a sterile sheath. The needle guides will support various sized needles. The needle guides are sold in sterile kits that contain multiple needle guides, sterile sheaths, ultrasound transmission gel, and bands.

Frequency Range	2-15MHz
Transducer types	Linear array Curved array TEE array Intracavity array Phased array

The SonixTouch Ultrasound Scanner is designed to comply with the following standards and the system follows Track 3.

EN 60601-1	European Norm, Medical Electrical Equipment
UL 2601-1	Underwriters Laboratories Standards, Medical Electrical Equipment
C22-2 No 601.1	Canadian Standards Association, Medical Electrical Equipment
EM 60601-1-2	European Norm, Collateral Standard, Electromagnetic Compatibility
IEC 60601-2-37	Particular requirements for the safety of ultrasonic medical diagnostic equipment
AIUM	Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment – Jan 1998
AIUM	Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices

3.0 Summary of Intended Uses

The SonixTouch Ultrasound Imaging System is intended for the following applications: Ophthalmic, Abdominal, Cardiac, Intraoperative (specific), Intraoperative Neurological, Fetal, Pediatric, Small Parts, Neonatal / Adult Cephalic, OB/GYN, Transesophageal, Transrectal, Transvaginal, Peripheral Vascular, Musculoskeletal conventional, Musculoskeletal superficial, Pelvic, Nerve block, Vascular Access, Transcranial, Intravascular, Laparoscopic.

The system also provides the ability to measure anatomical structures {fetal, abdominal, pediatric, small organ, cardiac, transrectal, transvaginal, peripheral vessel, musculo-skeletal} and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

4.0 Comparison to Predicate Device

The SonixTouch Ultrasound Scanner is substantially equivalent to the predicate devices with respect to intended use/indications for use, principles of operation and technological characteristics.

The SONIX Touch Ultrasound Scanner includes a digital beamformer that is similar in function to the predicate devices beamformer. It allows transmitting and receiving signals through the ultrasound transducers. The ultrasound transducers are similar to the ones used on predicate devices.

The backend processing is also similar to the predicate devices and yields an ultrasound image in realtime for diagnosis purposes.

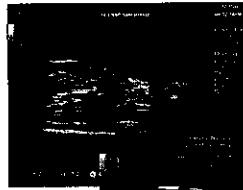
Elastography

The Elastography imaging mode is similar to the Siemens S2000 Elasticity imaging mode implementation (also called eSie Touch Elasticity Imaging).

The following slides explain the concept used for Elastography imaging:

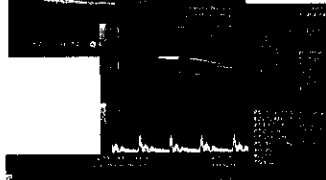
Elastography is a method to extract the mechanical properties of tissue

Comparison of Ultrasound Imaging Techniques



B-mode

Observe internal structure types and boundaries



Doppler modes

Observe internal flow and tissue motion

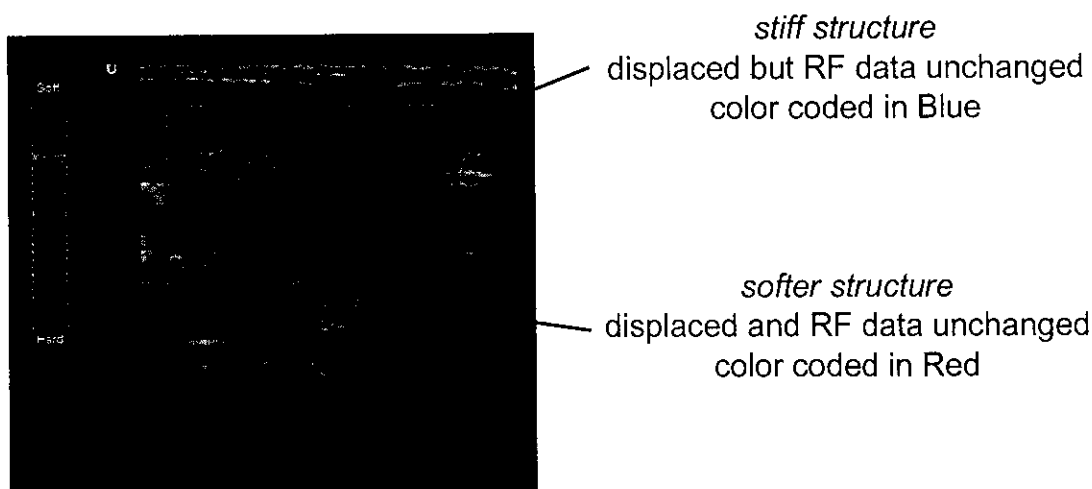


Elastography

Observe mechanical properties of tissue

The imaging method involves applying a mechanical pressure with the hand on the transducer. The actual imaging sequence is similar to the B-mode sequence except that the system will acquire the RF signal instead of acquiring B mode data. The acoustic output transmission is identical to B-mode. The algorithm extracts a strain value information for every point on the image. The Elastography image then color-codes the stiff versus softer structures. The clinical benefits of elastography imaging are still under evaluation and no clinical diagnosis claim can be made other than being able to tell whether or not a structure inside the patient is stiffer than another one. The submission includes a document "00.046.088_Ultrasonix_OP-SP_2.7.0_Release_Validation_Protocol_B_061308_ElastoValidation_Corina" included in the additional information dated October 14, 2008 which provides the verification protocol as well as expected results for elastography imaging. The report verifies the elasticity imaging algorithm (images actually in the validation protocol as well) can differentiate different structures with different rigidity

Elastography Imaging Technique



Elastography verification data

The attached document "00.046.088_Ultrasonix_OP-SP_2.7.0_Release_Validation_Protocol_B_061308_ElastoValidation_Corina" includes verification protocol as well as expected results for elastography imaging. The report verifies that our elasticity imaging algorithm (images actually in the validation protocol as well) passes and can differentiate different structures with different rigidity.

5.0 Technological characteristics

The technological characteristics are substantially similar to that of the predicates. The device operates identically to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D or M-mode images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, PW Doppler, Color Flow Mapping Doppler, Power Doppler, Continuous Wave Doppler) are the same as the predicate devices identified in item 2.5. Transducer patient contact materials are biocompatible.

The beam forming architecture is very similar to that of the predicate devices. The receiving and processing hardware is similar but innovative in that it is a programmable system made of 2 building blocks, which can be reconfigured to operate the system in any imaging mode.

The parameters used to adjust image quality are the same as that seen in the predicates. This includes the use of TGC gain, depth control, base control and angling, among others.

6.0 Safety considerations

As track 3 ultrasound device, the SonixTouch Ultrasound Scanner is designed to comply with the "Standard For Real Time Display Of Thermal And Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment (1992)" published by the National Electrical Manufacturers Association as UD-3.

With respect to limits on acoustic outputs, the SonixTouch Ultrasound Scanner complies with the guideline limits set in the September 30, 1997 revision of 510(k) Diagnostic Ultrasound Guidance.

With regard to general safety, the SonixTouch Ultrasound Scanner is designed to comply with IEC 601-1 (1988) Medical Electrical Equipment, Part 1: General Requirements for Safety, and IEC 60601-2-37: Particular Requirements For The Safety Of Ultrasonic Medical Diagnostic And Monitoring Equipment.

The devices' acoustic output limits are:

I _{SPTA} (d)	720mW/cm ²
TIS/TIB/TIC	0.1 – 4.0 (Range)
Mechanical Index (MI)	1.9 (Maximum)
I _{SPPA} (d)	0 – 700W/cm ² (Range)

The limits are the same as predicate Track 3 devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 5 - 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ultrasonix Medical Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K083095

Trade/Device Name: SonixTouch Ultrasound Scanner
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: October 16, 2008
Received: October 17, 2008

Dear Mr. Job:

This letter corrects our substantially equivalent letter of October 31, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SonixTouch Ultrasound System, as described in your premarket notification:

Transducer Model Number

SA4-2/24 Phased Array 2.8 MHz 24 mm
SA3-1/24 Phased Array 2.0 MHz 24mm
PA7-4 Phased Array 5.0 MHz
C5-2/60 Convex 3.2 MHz 60mm Radius
C5-2/40 Convex 3.2 MHz 40mm Radius
C7-3/50 Convex 5.0 MHz 50mm Radius
EC9-5/10 Microconvex Endocavity 6.6 MHz 10mm Radius
L14-5/38 Linear 8 MHz 38mm
L9-4/38 Linear 6.5 MHz 38mm
L14-5W/60 Linear 8 MHz 38mm

BPSL9-5/55/10L Linear ECBP 7.5 MHz
BPSL9-5/55-10C Microconvex ECBP 6.5 MHz
4DC7-3/40mm 3D/4D Curved Transabdominal 3.5 MHz
4DEC9-5/10mm 3D/4D Endocavity 6.5 MHz
MC9-4/12mm Microconvex 6.0 MHz
4DL14-5/38mm 3D/4D Linear 7.5 MHz
HST15-8/20mm Hockey Stick Linear 10.0 MHz
L15-8/26mm Linear 10.0 MHz
TEM7-3/9mm Transesophageal 5.0 MHz
TEM10-7/5mm Transesophageal 7.0 MHz
TEEIMA Transesophageal 7.0 MHz
LAP Laproscopic

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Sunder Rajan at (240) 276-3666.

Sincerely yours,


for Janine M. Morris

Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known):

Device Name: SonixTouch Ultrasound Scanner

Indications For Use:

The SonixTouch Ultrasound Scanner is intended for the following applications:
Ophthalmic, Abdominal, Cardiac, Intraoperative (specific), Intraoperative
Neurological, Fetal, Pediatric, Small Parts, Neonatal/ Adult Cephalic, OB/GYN,
Transesophageal, Transrectal, Transvaginal, Peripheral Vascular,
Musculoskeletal conventional, Musculoskeletal superficial, Pelvic, Nerve Block,
Vascular Access, Transcranial.

The system also provides the ability to measure anatomical structures {fetal, abdominal, pediatric, small organ, cardiac, transrectal, transvaginal, peripheral vessel, musculoskeletal} and provides calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

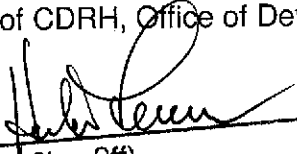
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K083095

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ULTRASOUND INDICATIONS FOR USE TABLES

SonixTouch Ultrasound Scanner – Diagnostic Ultrasound Indications for Use Form

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic		N	N	N		N	N	N	N (*1)	N (*2)
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N	N	N	N	N	N (*1)	N (*2)
Intraoperative (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative Neurological		N	N	N		N	N	N	N (*1)	N (*2)
Pediatric		N	N	N	N	N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac		N	N	N	N	N	N	N	N (*1)	N (*2)
Transesophageal		N	N	N		N	N	N	N (*1)	N (*2)
Transrectal		N	N	N		N	N	N	N (*1)	N (*2)
Transvaginal		N	N	N		N	N	N	N (*1)	N (*2)
Transurethral										
Transcranial		N	N	N		N	N	N	N (*1)	N (*2)
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Laparoscopic		N	N	N		N	N	N	N (*1)	N (*2)
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Vascular Access		N	N	N		N	N	N	N (*1)	N (*2, *4)
Nerve Block		N	N	N		N	N	N	N (*1)	N (*2, *3)
Other (specify)										

N = New indication; **P** = Previously cleared

Additional Comments:

Small Organ: Breast, Thyroid, Testicle

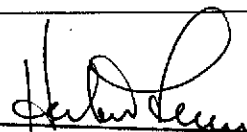
Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging, Live 3D/4D Imaging.

*3. Imaging for guidance of nerve block injections

*4. Imaging for guidance of central or peripheral lines.


(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
SA4-2/24 phased array 2.8 MHz 24mm transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N	N	N (*1)	N (*2)
Small Organ (specify)										
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N	N	N	N	N	N (*1)	N (*2)
Cardiac		N	N	N	N	N	N	N	N (*1)	N (*2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Transcranial		N	N	N	N	N	N	N	N (*1)	N (*2)
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; P = Previously cleared

Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging


 (Division Sign-Off)

Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
SA3-1/24 phased array 2.0 MHz 24mm transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N	N	N (*1)	N (*2)
Small Organ (specify)										
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N	N	N	N	N	N (*1)	N (*2)
Cardiac		N	N	N	N	N	N	N	N (*1)	N (*2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Transcranial		N	N	N	N	N	N	N	N (*1)	N (*2)
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; **P** = Previously cleared

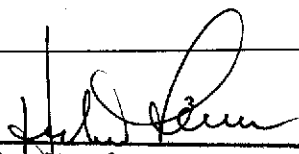
Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.


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 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
PA7-4 phased array 5.0 MHz transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N	N	N (*1)	N (*2)
Small Organ (specify)										
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N	N	N	N	N	N (*1)	N (*2)
Cardiac		N	N	N	N	N	N	N	N (*1)	N (*2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Transcranial		N	N	N	N	N	N	N	N (*1)	N (*2)
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; **P** = Previously cleared


Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.


 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
C5-2/60 convex 3.2 MHz 60mm radius transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Transcranial										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Laparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; **P** = Previously cleared

Additional Comments:

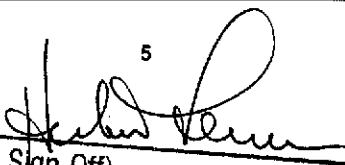
Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.

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 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
C5-2/40 convex 3.2 MHz 40mm radius transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Transcranial										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Laparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; P = Previously cleared

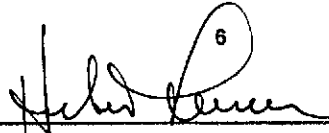
Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.


 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
C7-3/50 convex 5.0 MHz 50mm radius transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Transcranial										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Laparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; **P** = Previously cleared

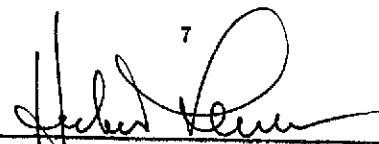
Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.

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 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
EC9-5/10 microconvex endocavity 6.6 MHz 10mm radius transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N	N	N (*1)	N (*2)
Transvaginal		N	N	N		N	N	N	N (*1)	N (*2)
Transurethral										
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; P = Previously cleared

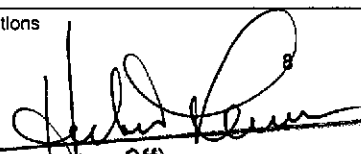
Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.


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Division of Reproductive, Abdominal and
 Radiological Devices

510(k) Number 14083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
L14-5/38 linear 8 MHz 38mm transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Laparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Vascular Access		N	N	N		N	N	N	N (*1)	N (*2, *4)
Nerve Block		N	N	N		N	N	N	N (*1)	N (*2, *3)
Other (specify)										

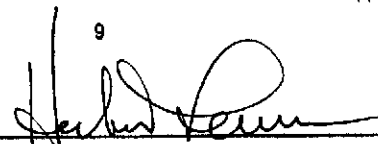
N = New indication; **P** = Previously cleared

Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

- *1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
- *2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.
- *3. Imaging for guidance of nerve block injections
- *4. Imaging for guidance of central or peripheral lines.

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 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number 6083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
L9-4/38 linear 6.5 MHz 38mm transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Laparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Vascular Access		N	N	N		N	N	N	N (*1)	N (*2, *4)
Nerve Block		N	N	N		N	N	N	N (*1)	N (*2, *3)
Other (specify)										

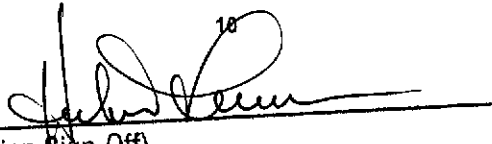
N = New indication; P = Previously cleared

Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

- *1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
- *2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.
- *3. Imaging for guidance of nerve block injections
- *4. Imaging for guidance of central or peripheral lines.


 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number 14083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
L14-5W/60 linear 8 MHz 38mm transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Laparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Vascular Access		N	N	N		N	N	N	N (*1)	N (*2, *4)
Nerve Block		N	N	N		N	N	N	N (*1)	N (*2, *3)
Other (specify)										

N = New indication; P = Previously cleared

Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

- *1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
- *2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.
- *3. Imaging for guidance of nerve block injections
- *4. Imaging for guidance of central or peripheral lines.


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Division of Reproductive, Abdominal and
 Radiological Devices

510(k) Number

K083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
BPSL9-5/55-10L linear ECBP 7.5 MHz transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N	N	N	N	N	N (*1)	N (*2)
Transvaginal										
Transurethral										
Transcranial										
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; **P** = Previously cleared

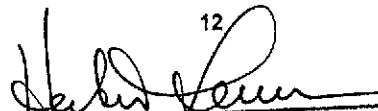
Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.

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 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K083099

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
BPSL9-5/55-10C microconvex ECBP 6.5 MHz transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N	N	N	N	N	N (*1)	N (*2)
Transvaginal										
Transurethral										
Transcranial										
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; **P** = Previously cleared

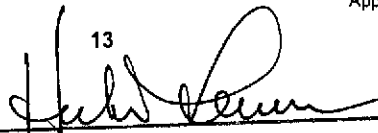
Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.


 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
4DC7-3/40mm 3D/4D Curved Transabdominal 3.5 MHz transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Transcranial										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Laparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; P = Previously cleared

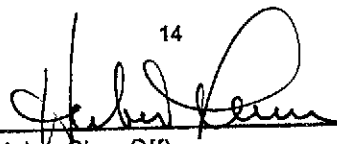
Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging, Live 3D/4D Imaging.


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 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number 15083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
4DEC9-5/10mm 3D/4D Endocavity 6.5 MHz transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N	N	N	N	N	N (*1)	N (*2)
Transvaginal		N	N	N	N	N	N	N	N (*1)	N (*2)
Transurethral										
Transcranial										
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; **P** = Previously cleared

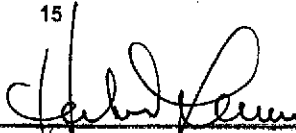
Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging, Live 3D/4D Imaging.

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 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
MC9-4/12mm microconvex 6.0 MHz transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N	N	N (*1)	N (*2)
Small Organ (specify)										
Neonatal Cephalic		N	N	N	N	N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N	N	N	N	N	N (*1)	N (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Transcranial		N	N	N	N	N	N	N	N (*1)	N (*2)
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Vascular Access		N	N	N		N	N	N	N (*1)	N (*2, *4)
Nerve Block		N	N	N		N	N	N	N (*1)	N (*2, *3)
Other (specify)										

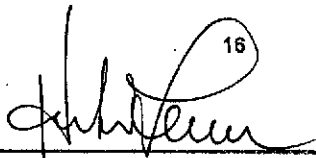
N = New indication; **P** = Previously cleared

Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

- *1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
- *2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.
- *3. Imaging for guidance of nerve block injections
- *4. Imaging for guidance of central or peripheral lines.


 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number 15083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
4DL14-5/38mm 3D/4D Linear 7.5 MHz transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Transcranial										
Peripheral Vascular										
Laparoscopic		N	N	N		N	N	N	N (*1)	N (*2)
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Vascular Access		N	N	N		N	N	N	N (*1)	N (*2, *4)
Nerve Block		N	N	N		N	N	N	N (*1)	N (*2, *3)
Other (specify)										

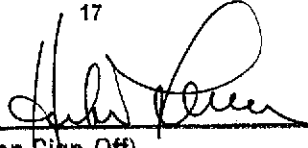
N = New indication; **P = Previously** cleared

Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

- *1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
- *2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging, Live 3D/4D Imaging.
- *3. Imaging for guidance of nerve block injections
- *4. Imaging for guidance of central or peripheral lines.

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 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
HST15-8/20mm hockey stick linear 10.0 MHz transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic		N	N	N		N	N	N	N (*1)	N (*2)
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological		N	N	N		N	N	N	N (*1)	N (*2)
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Transcranial		N	N	N		N	N	N	N (*1)	N (*2)
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Laparoscopic		N	N	N		N	N	N	N (*1)	N (*2)
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Vascular Access		N	N	N		N	N	N	N (*1)	N (*2, *4)
Nerve Block		N	N	N		N	N	N	N (*1)	N (*2, *3)
Other (specify)		N	N	N		N	N	N	N (*1)	N (*2)

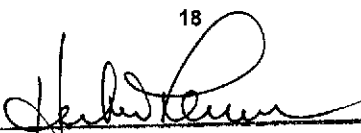
N = New indication; **P** = Previously cleared

Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

- *1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
- *2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.
- *3. Imaging for guidance of nerve block injections
- *4. Imaging for guidance of central or peripheral lines.


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 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
L15-8/26mm linear 10.0 MHz transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic		N	N	N		N	N	N	N (*1)	N (*2)
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological		N	N	N		N	N	N	N (*1)	N (*2)
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Transcranial		N	N	N		N	N	N	N (*1)	N (*2)
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Laparoscopic		N	N	N		N	N	N	N (*1)	N (*2)
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Vascular Access		N	N	N		N	N	N	N (*1)	N (*2, *4)
Nerve Block		N	N	N		N	N	N	N (*1)	N (*2, *3)
Other (specify)		N	N	N		N	N	N	N (*1)	N (*2)

N = New indication; P = Previously cleared

Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

- *1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
- *2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.
- *3. Imaging for guidance of nerve block injections
- *4. Imaging for guidance of central or peripheral lines.

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Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

2083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
TEM7-3/9mm transesophageal 5.0 MHz transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		N	N	N	N	N	N	N	N (*1)	N (*2)
Transrectal										
Transvaginal										
Transurethral										
Transcranial										
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; **P** = Previously cleared

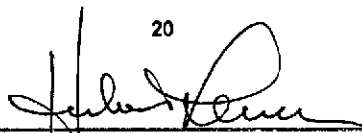
Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.



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 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number 15083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
TEM10-7/5mm transesophageal 7.0 MHz transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		N	N	N	N	N	N	N	N (*1)	N (*2)
Transrectal										
Transvaginal										
Transurethral										
Transcranial										
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; P = Previously cleared

Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.

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Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
TEE/IMA transesophageal 7.0 MHz transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		N	N	N	N	N	N	N	N (*1)	N (*2)
Transrectal										
Transvaginal										
Transurethral										
Transcranial										
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Vascular Access										
Nerve Block										
Other (specify)										

N = New Indication; P = Previously cleared

Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.

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Division of Reproductive, Abdominal and
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510(k) Number K083095

Diagnostic ULTRASOUND INDICATIONS FOR USE Form
LAP Laparoscopic transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Transcranial										
Peripheral Vascular										
Laparoscopic		N	N	N	N	N	N	N	N (*1)	N (*2)
MSK Conventional										
MSK Superficial										
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; P = Previously cleared

Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2. Elastography, Directional Power Doppler (DPD), Imaging for guidance of biopsy, Panoramic Imaging, Harmonic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging.

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510(k) Number

K083095